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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,746	07/26/2001	Yajun Guo	22163-0003002	1834
26191 7590 12/04/2008 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER				
CANELLA, KAREN A				
ART UNIT		PAPER NUMBER		
1643				
NOTIFICATION DATE		DELIVERY MODE		
12/04/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

# Office Action Summary

**Application No.**

09/915,746

**Applicant(s)**

GUO ET AL.

**Examiner**

Karen A. Canella

**Art Unit**

1643

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 15-17 is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) 19, 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date: \_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

Claims 2-4, 6, 8-13 and 18 have been canceled. Claims 19 and 20 have been added. Claims 14-17, 19 and 20 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 14 is rejected under 35 U.S.C. 102(a) as being anticipated by the abstract of Trefzer et al (Journal of Dermatological Science, March 1998, Vol. 16, suppl. 1, page S110, reference 57 of the IDS submitted October 4, 2002, cited in a previous Office action).

The abstract of Trefzer et al discloses a method for detecting the presence of melanoma in a human host comprising contacting a tissue sample with the SM5-1 monoclonal antibody and detecting the formation of immune complexes as indicative of melanoma. The abstract discloses that the SM5-1 detected melanoma in paraffin-embedded melanocytic tissues by means of the APAAP-technique for staining the tissues, thus fulfilling the specific embodiment of an enzyme as a detectable label.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the abstract of Chen et al (Journal of Molecular Medicine, May 1998, Vol. 76, page B11, cited in a previous Office action) in view of Kerr and Thorpe (Immunochemistry LabFax, pages xi, X and 120).

The specification states that the SM5-1 antibody was deposited under the Accession number HB-12588 (page 4, lines 10-11)..

The abstract of Chen et al teaches that the SM5-1 antibody binds to human fibronectin and the immunohistochemical analysis of samples using said antibody . The abstract discloses a method for detecting the presence of melanoma in a human host comprising contacting a tissue sample with the SM5-1 monoclonal antibody and detecting the formation of immune complexes as indicative of melanoma. The abstract did not specifically teach that the antibody was conjugated to a label which produces a detectable signal, but the abstract did teach flow cytometric analysis, immunoprecipitation, Western blot and immunohistology using the SM5-1 antibody.

Kerr and Thorpe teach the labeling of antibodies with enzymes (page x, under the index for chapter 7), fluorescers, (pages x-xi, under the heading for chapter 8) and the use of said labeled antibodies in common immunological techniques (page XI, under the heading for chapter 9). Kerr and Thorpe teach that radiolabeled antibodies are useful for determining avidity and specificity of an antibody (page 120, Table 2)

It would have been prima facie obvious to label the SM5-1 antibody with an enzyme, fluorescent moiety or radionuclide. One of skill in the art would have been motivated to do so by the teachings of Kerr and Thorpe regarding the use of labeled antibodies in immunochemical assays.

Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 15-17 are free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643